**A one page description of the proposed experiment in non-technical language**

This study is designed to evaluate the safety and effectiveness of an investigational therapy treatment for breast cancer using a new "vaccine" preparation in patients with advanced breast cancer which cannot be cured by currently available standard treatments (surgery, chemotherapy, hormonal therapy or radiation therapy). The vaccine is prepared by surgically removing one of the metastatic lesions from body as part of needed clinical care and mechanically disrupting the tumor cells in the test tube. Tumor cells will then be modified by insertion of DNA or genetic material (a "gene"). This modification will result in the production of a protein substance called interleukin 2 (IL-2) within the tumor cells. The modified tumor cells are then used as a "vaccine" against cancer. The IL-2 produced by the modified tumor cells will hopefully cause the immune system to attack the tumor cells. The modified tumor cells are called Autologous Interleukin 2 Gene Modified Tumor cells ("GMT"). This research study is designed to test safety and effectiveness of this "GMT" in terms of stimulating the body 's immune system to attack the metastatic cancer.

The gene or DNA is inserted into the tumor cells in the laboratory using genetic engineering techniques that have recently been developed. The DNA is inserted into a substance (vector) which is not a virus and does not grow but acts as a vehicle to deliver the gene which would otherwise not be efficiently incorporated into the tumor cells. The gene has the capability of making the tumor cells express and produce human IL-2. The tumor cells will be killed with radiation before injecting into the body. The IL-2 gene vector is an experimental agent, called Avectin$^{TM}$, produced at Applied Immune Sciences, Inc. Under Dr. H. Kim Lyerly's direction, the IL-2 gene will be incorporated into the tumor cells to produce the "GMT".

If a patients chooses to enter this program, they will be injected with "GMT" every four weeks for four months until they have received four (4) total injections. The duration of this study will be 36 months on an out-patient basis, and the patient will be followed for the rest of their life after vaccination for clinical evaluation. Each injection will be given in the soft tissue of the body (subcutaneously). The "GMT" will be prepared under stringent conditions and will be tested for sterility. Similar modified tumor cells have been tested in mice and have been found to have some ability to counteract the growth of tumor. Several studies involving laboratory animals have shown an increased immune response and reduction of tumor size with these preparations. Several trials in humans have begun, including one at Duke, and the results are not known at this time. I

Blood tests will be done to evaluate the safety and effectiveness of this research. The blood will be obtained by venipuncture (needle stick in a blood vessel in arm) and will total 300cc over the 36 months of this study, which is 3/5 of a pint. This is the standard method for obtaining blood and is momentarily painful. There is a small risk of fainting, of some bruising (bleeding under the skin), and a rare (1/1000) risk of infection. We will also be doing other routine laboratory or radiologic studies. These tests include a urinalysis and other blood chemistries. These studies would also be done for the breast cancer check-up. All other tests are considered standard care and no additional tests will be done that are not part of the standard care.